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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/455,683	05/31/1995	GRAEME I. BELL	ARCD:177/WIM	8952

7590 08/19/2002

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EXAMINER

LANDSMAN, ROBERT S

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 08/19/2002

40

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/455,683

Applicant(s)

BELL ET AL.

Examiner

Robert Landsman

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2002.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 91-109, 112-114, 116-123, 125-132, 134, 135 and 137-143 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 91-96, 103-108, 116-122, 125-132, 134 and 135 is/are allowed.
- 6) ☒ Claim(s) 97-102, 109, 112-114, 123 and 137-143 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

1. Formal Matters

- A. Amendment J, filed 6/19/02, has been entered into the record.
- B. Claims 91-109, 112-114, 116-123, 125-132, 134, 135 and 137-143 are pending in this application.
- C. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

2. Claim Rejections - 35 USC § 112, first paragraph – written description

A. Claims 97-102, 109, 112-114, 123, 137 and 143 remain rejected under 35 USC 112, first paragraph, and claims 138-142 are also rejected for the reasons already of record on pages 2-3 of the Office Action dated 3/12/02. In Amendment H, filed 12/10/01, claims 138-142 recited, or depended from claims which recite SEQ ID NO:1. However, in Amendment J, filed 6/19/02, claims 138-142 recited, or depended from claims which recite SEQ ID NO:11. Therefore, claims 138-142 are being included in this rejection under 35 USC 112, first paragraph, since they now recite "SEQ ID NO:11." Applicants argue that they were in possession of SEQ ID NO:11 at the time of the invention and that patent law does not require Applicants to limit specifically their invention only to embodiments reduced to practice. Therefore, for example, constructs such as the full-length receptor and chimeras using SEQ ID NO:11 can be utilized by the claimed methods. They further argue that it is irrelevant whether additional sequences are attached to the claimed compositions and that the methods claimed utilize novel and non-obvious characteristics of the polynucleotides and polypeptides disclosed. However, the issue remains that SEQ ID NO:11 is not a full-length receptor and Applicants are claiming a method of screening a substance for its ability to bind an opioid receptor by expressing a receptor comprising at least 30-100 contiguous bases of SEQ ID NO:11 when Applicants do not know the sequence of, and are therefore not in possession of, the full-length receptor. Furthermore, since Applicants are not in possession of the full-length receptor, they are not able to identify which amino acids encoded for by the polynucleotide of SEQ ID NO:11 are required for binding of a ligand to the receptor encoded for by SEQ ID NO:11. The fact that the claims recite a method for screening for compounds which affect an opioid receptor, implying that Applicants are reaching for the full-length receptor. In addition, Applicants argue that constructs such as chimeras are

Art Unit: 1647

encompassed by these claims. As argued in the previous Office Action, Applicants would either need to use "consisting of" language in order to prevent the claims from reading on the full-length receptor, or to recite that the nucleic acids of the claimed processes would only be able to "comprise" up to the full-length of SEQ ID NO:11. The use of "consisting of" language or "comprising up to the full-length of SEQ ID NO:11" would still allow the claims to encompass various constructs such as chimeras without encompassing the full-length receptor.

3. Claim Rejections - 35 USC § 112, first paragraph - enablement

A. The rejection of all claims under 35 USC 112, first paragraph, regarding the use of SEQ ID NOs instead of the single-letter abbreviations in the claims, has been withdrawn since Applicants have amended the claims to recite SEQ ID NOs.

4. Claim Rejections - 35 USC § 112, second paragraph

A. The rejection of claims 138-142 under 35 USC 112, second paragraph, regarding the recitation of SEQ ID NO:1, has been withdrawn since Applicants have amended the claims to recite SEQ ID NO:1.

5. Conclusion

A. Claims 91-96, 103-108, 116-122, 125-132, 134 and 135 are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Application/Control Number: 08/455,683

Page 4

Art Unit: 1647

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
August 15, 2002

Gary L. Kunz